

**Notice of Allowability**

Application No.

10/724,301

Examiner

Malgorzata A. Walicka

Applicant(s)

ENENKEL ET AL.

Art Unit

1652

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 06/06/06.
2. ☒ The allowed claim(s) is/are 1-5,9,11,16,24 and 32.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of the:
- ☒ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application                     |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance  |
|  | 9. <input checked="" type="checkbox"/> Other <u>See Continuation Sheet</u> .          |

Continuation of Attachment(s) 9. Other: page 4 of 4 of the IDS of 07/12/04..

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Amendment of June 6, 2006 is acknowledged. Claims 1, 2, 3, 14, 15, 16, 24 and 32 have been amended. Claims 1-54 are pending. The elected claims 1-5, 9, 11, 16, 24 and 32 are under examination. Claims 6-8, 10, 12-15, 17-23, 25-31 and 33-54 are withdrawn from examiner's consideration as directed to a non-elected invention.

## **DETAILED ACTION**

### **1. Priority**

Acknowledgment is made of English translation of priority documents, i.e. German Patent applications 102 56 081, filed 11/29/2002 and 10330686, filed 7/08/2003. The priority of the instant claims to the German application 10330686, filed 7/08/2003 has been granted. The priority of the instant claims to the German application 102 56 081, filed 11/29/2002 has not been granted, because this application does not contain the subject matter of claims 1-5, 9, 11, 16, 24 and 32.

Acknowledgment is made of filing a copy of English translation of the provisional application 60/487,902 filed 07/17/2003. Priority of the instant claims to 60/487,902 has been granted.

### **2. Objections**

Objection to claim 16 made in the Office action of March 8, 2006 (previous action) is withdrawn, because the claim has been amended.

Objections to Fig 5 and 6 made in the previous action is withdrawn, because the figures have been corrected.

### **3. Rejections**

#### **3.1. 35 USC section 112, second paragraph**

Claims 1-3 and 9-11, 24 and 32 were rejected under 35 U.S.C. 112, second paragraph in the previous action. This rejection is withdrawn, because the claims have been amended.

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### **3.2. 35 USC section 112, first paragraph**

#### **3.2.1. Written description**

Rejection of claims 1-3 and 9-11, 24 and 32 for the reasons explained in the previous Office Action is withdrawn, because the claims have been amended.

Objections to claims 4-5 as depending on rejected claim 1 is withdrawn, because claim 1 has been amended.

#### **3.2.2. Scope of enablement**

Claims 1-3, 9-11 and 24 were rejected in the previous action. This rejection is now withdrawn, because the claims have been amended.

Objections to claims 4-5 as depending on the rejected claim 1 are withdrawn, because claim 1 has been amended.

### **4. Examiner's amendment**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

(a) Please amend claim 1 as follows.

1. A modified neomycin phosphotransferase gene wherein the modified neomycin phosphotransferase gene encodes a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 with the modification that the amino acid [encoded] at position 91 and/or 198 and or 240 is a different amino acid than that of SEQ ID NO:2.

(b) Please cancel claims 6-8, 10, 12-15, 17-23, 25-31 and 33-54 directed to the non elected invention.

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Authorization for this examiner's amendment was given in a telephone interview with Paula K. Wittmayer on Sept. 13, 2006.

## 5. Allowance

Claims 1-5, 9, 11, 16, 24 and 32 are allowed. The following is the examiner's reason for allowance. Applicants disclose new mutants of neomycin phosphotransferase of *E. coli* (SEQ ID NOs: 6, 8, and 18) and their encoding DNA sequences (SEQ ID NOs: 5, 7, and 17). The new mutants of the enzyme have lower activity than the wild type. The wild type enzyme confers resistance to various aminoglycoside antibiotics by transferring the terminal phosphate from ATP to the 3' hydroxyl group of the aminohexose ring I, and for that reasons the wild type gene is routinely used as selective marker for cells transfected with any gene encoding biopharmaceutical proteins wherein the cells are used for production of these proteins. When these cells are transfected with a gene coding neomycin transferase of lower than normal activity, the selective pressure on the transfected cells is lower, which allows production of high number of transfected cells to be used in biopharmaceutical production. Applicants also claim expression vector containing the mutated gene, cells transfected with said vector and a method for enrichment of population of mammalian cells that express the disclosed modified neomycin – phosphatase gene. Although the prior art teaches the use of gene encoding the neomycin phosphotransferase having lower activity (WO 99/53046, Asp261Asn, expressed in production-relevant mammalian cells), no prior art teaches the gene modified so that the mutated proteins are identified by SEQ ID NO: 6, 8, and 18. Thus the claimed sequences are new products, and the methods of using them are also new.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Patent Examiner

  
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